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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,988	09/24/2001	Jeffrey Schlom	2026-4292US1	7849

7590 01/27/2003

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/27/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,988

Applicant(s)

SCHLOM ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 106 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-106 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 7-35, 75-81, drawn to a recombinant vector, a composition comprising at least three costimulatory molecules and an antigen, and a method for using the composition enhancing an immune response.

Group II, claim(s) 1, 5, 7-35, 75-81, drawn to a recombinant vector and a composition comprising costimulatory molecules of B7-1, ICAM-1 and LFA-3 and an antigen, and a method for using the composition enhancing an immune response.

Group III, claim(s) 1, 6, 7-36, 75-81, drawn to a recombinant vector and a composition comprising costimulatory molecules and an antigen plus a foreign sequence encoding at least a cytokine, Flt-3L or chemokine and a method for using the composition enhancing an immune response.

Group IV, claim(s) 37, 89-93, drawn to a host cell comprising a recombinant vector encoding multiple costimulatory molecules and an antigen and a method for treating or preventing a disease.

Group V, claim(s) 38-44, 89-93, drawn to a host cell comprising a recombinant vector encoding multiple costimulatory molecules and an antigen and a method for treating or preventing a disease.

Group VI, claim(s) 45, 47-53, 94, 96-99, drawn to a dendritic cell, a composition and a method for using the composition comprising the dendritic cell, which carries a foreign nucleic acid sequence encoding multiple costimulatory molecules and a target antigen or immunological epitope sequence.

Group VII, claim(s) 46, 47-53, 95-99, drawn to a tumor cell, a composition and a method for using the composition comprising the tumor cell, which comprises a foreign nucleic acid

Art Unit: 1648

sequence encoding multiple costimulatory molecules plus a target antigen or immunological epitope sequence.

Group VIII, claim(s) 54, 56-63, drawn to a recombinant poxvirus and a host cell infected with the recombinant poxvirus having an integrated foreign DNA encoding multiple costimulatory molecules and an antigen.

Group IX, claim(s) 55, 56-63, drawn to a recombinant poxvirus and a host cell having an integrated foreign DNA encoding LFA-3, ICAM-1 and B7 molecules and an antigen.

Group X, claim(s) 64-66, 71, 73, 74, drawn to a plasmid vector, a kit and method for making the vector comprising nucleic acid sequences encoding multiple costimulatory sequences designated as pT5064.

Group XI, claim(s) 64, 67-69, 72, 73, 74, drawn to a plasmid vector, a kit and a method for making a vector comprising nucleic acid sequences encoding multiple costimulatory sequences plus an antigen or immunological epitope designated as pT5049.

Group XII, claim(s) 70, 73, 74, drawn to a plasmid vector, a kit and a method for making a vector of a recombinant poxvirus expressing foreign nucleic acid sequence encoding three costimulatory molecules of LFA-3, ICAM-1 and B7.

Group XIII, claim(s) 82-88, drawn to a method for enhancing an antigen-specific T cell response comprising using a poxvirus vector encoding B7, ICAM-1 and LFA-3, optionally with an antigen or epitope sequence.

Group XIV, claim(s) 100-103, drawn to a method for making a progenitor dendritic cell.

Group XV, claim(s) 104, drawn to an in vitro assay for assessing efficacy of a vaccine against a target antigen.

Group XVI, claim(s) 105-106, drawn to a method for screening a novel immunogenic peptide.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of a recombinant vector of group I, which encodes multiple costimulatory molecule, has been taught in the prior art as evidenced by Schlom et al. (WO096/10419A3) and Hauser et al. (EP 0 803 573A1). Schlom et al. disclose a recombinant vector comprising a multiple costimulatory molecules, such

Art Unit: 1648

as B7.1 and B7.2 (Claims 10-11 and 17) and a method for using the vector for enhancing an immune response (see entire document). Hauser et al. teach that a polycistronic expressing construct of a vector encoding more than two genes of a cytokines (Claims 9-10) and a method for enhancing the immune response (see entire document).

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of the vectors:

A). A bacterial vector. B). A virus vector. C). A nucleic acid vector.

Claims 1, 34, 35, 36, 37, 38, 54, 55, 100 and 105 are generic. If group B is elected, please further select one of the viral vectors listed on claim 11. If Poxvirus is elected please further elect one of the poxvirus listed on claim 14. If avipox virus is elected, please further select one of the virus listed on claim 15. if orthpox virus is elected, please further select one of the virus listed on claim 16.

The species of the antigens are:

SEQ ID NO: 2-40. Claim 17 is generic. Please further elect one of the sequences for the prosecution on the merits.

The species of antigens are listed on claims 19 and 68. Claims 19 and 68 are generic.

If bacterial antigen is elected, please elect one of the bacterial antigens listed on claim 20. If viral antigen is elected, please further elected one of the viral antigens listed on claim 21. If tissue specific antigen is selected, please further select one of the tissue antigen listed on claim 26. If yeast or fungus antigen is elected, please further select one of the antigen listed on claim 30. If a parasite antigen is elected, please further selected one of the parasite antigen listed on claim 31.

The species of host cells:

a). an antigen presenting cell, b). a premalignant cell, c). a hyperplastic cell, d). a tumor cell.

Claims 37, 38, 39, 60, 104 are generic. Please select one of the host cell for the prosecution on the merits.

Art Unit: 1648

If a) is elected, please further select one of the following species of the antigen presenting cells: i). Dendritic cell, ii). Monocyte, iii). Macrophage, iv). B-cell, v). Fibroblast cell, vi).

Muscle cell.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: for example, the bacterial vector has different structure and function than the viral vector; the antigen presenting cell is structurally and functionally different than the tumor cell; the dendritic cell is structurally and functionally different from B-cell, and the SEQ ID NO: 2 is structurally and functionally different than SEQ ID NO: 40.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1648

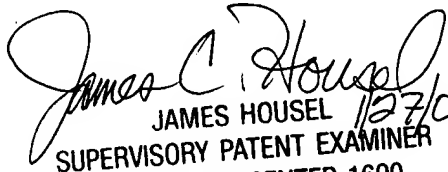
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

January 23, 2003


JAMES HOUSEL 1/27/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600